Docket No.: VAS-5041CIP2

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Dated: September 14, 2005 Name of Person Certifying: Melissa Sanchez
Printed Name:

BEFORE THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Shannon) Group Art Unit: 3738
)
Application No.: 09/997,829) Examiner: Brian E. Pellegrino
)
Filing Date: November 29, 2001)
)
For: RADIALLY EXPANDABLE)
TUBULAR STENT GRAFTS)
)

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SUPPLEMENTAL
APPEAL BRIEF UNDER 37 C.F.R. §41.37

Dear Sir:

This is an appeal from the final rejections of claims 103-119 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,700,285 to Myers, et al. in view of U.S. Patent No. 4,131,648 to Choi, et al. For the reasons discussed below, Applicants request reversal of the rejection and allowance of the claims.

The Notice of Appeal was filed on October 4, 2004, making this Appeal Brief timely.

This SUPPLEMENTAL Appeal Brief includes the headings ix. And x. as required by the BPAI ORDER mailed September 7, 2005.

i.

REAL PARTY IN INTEREST

The real party in interest is Edwards Lifesciences Corporation of Irvine, California.

Application No.: 09/997,829
Filing Date: November 29, 2001
SUPPLEMENTAL Appeal Brief filed September 14, 2005
Responsive to Final Office Action Dated June 2, 2004

ii.

RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

iii.

STATUS OF THE CLAIMS

Claims 103-119 stand rejected and appear in the attached claims appendix.

iv.

STATUS OF AMENDMENTS

An Amendment After Final under 37 C.F.R. §1.116 was filed on November 29, 2004 containing no claim amendments. That amendment merely canceled the priority claim.

v.

SUMMARY OF CLAIMED SUBJECT MATTER

The invention in sole independent claim 103 pertains to an implantable drug eluting device including a radially expandable stent having a polymer/therapeutic substance coating on a wall surface thereof, and a tubular outer layer comprising PTFE tape wound about the outer surface of the stent. The stent and tubular outer layer are described, for example, in paragraph [0092], while the coating is described at paragraph [0093]. FIGS. 4a-4f are step-by-step illustrations of a preferred method for manufacturing a drug eluting radially expandable tubular stented graft, some of which may be used in the construction of a drug eluting device as defined in claim 103.

vi.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1) Whether claims 103-105, 107, and 113-117 are not patentable under 35 U.S.C §103(a) as being obvious over U.S. Patent No. 5,700,285 to Myers, et al. in view of U.S. Patent No. 4,131,648 to Choi et al.
2) Whether claim 106 is not patentable under 35 U.S.C §103(a) as being obvious over Myers, et al. in view of Choi et al., and further in view of U.S. Patent No. 6,287, 285 to Michal, et al.
3) Whether claims 108-111 are not patentable under 35 U.S.C §103(a) as being obvious over Myers, et al. in view of Choi et al., and further in view of U.S. Patent No. 6,053,940 to Wijay, et al.
4) Whether claims 108-110, and 112 are not patentable under 35 U.S.C §103(a) as being obvious over Myers, et al. in view of Choi et al., and further in view of U.S. Patent No. 6,117,165 to Becker, et al.
5) Whether claims 118, 119 are not patentable under 35 U.S.C §103(a) as being obvious over Myers, et al. in view of Choi et al., and further in view of U.S. Patent No. 5,749,880 to Banas, et al.

vii.

ARGUMENT

1) Rejection of claims 103-105, 107, and 113-117 over Myers et al. in view of Choi et al.

Applicant respectfully submits that Myers in combination with Choi does not render the pending claims obvious to one of ordinary skill in the art, primarily because the Examiner has not established a *prima facie* case of obviousness.

The U.S. Court of Appeals for the Federal Circuit has held that "[t]he PTO has the burden under section 103 to establish a *prima facie* case of obviousness...It can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one

of ordinary skill in the art would lead that individual to combine the relevant teachings of the references." In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1595, 1598 (Fed. Cir. 1988).

Applicant respectfully submits that there is no basis which would support the combination of Myers and Choi to make the pending claims obvious. The Examiner is correct in asserting that Choi teaches an erodible coating that comprises a therapeutic agent. However, the Examiner's assertion that Choi teaches an implantable device coated with an erodible polymer is incorrect. Choi teaches that the erodible polymers disclosed in Choi "can be made into" implantable devices (see Choi, col. 28, ll. 15-17) but that is very different from coating an implantable device such as a stent-graft with a drug-containing polymer. Thus, Choi offers no teaching of coating an implantable device with the erodible polymers that it discloses.

Needless to say, Choi offers no suggestion whatsoever that a stent or graft can be coated with the polymers disclosed in Choi. In fact, Choi does not once mention either the term "stent" or the term "graft." Therefore, Choi provides no motivation that would lead one of ordinary skill in the art to combine Choi with Myers to make the claimed invention obvious.

"The examiner bears the burden of establishing a *prima facie* case of obviousness." ; In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). Only if the burden of establishing a *prima facie* case of obviousness is met by the Examiner, does the burden of coming forward with rebuttal argument or evidence shift to the applicant. In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). When the references cited by the examiner fail to establish a *prima facie* case of obviousness, the rejection is improper and will be overturned. Fine, 837 F.2d at 1074, 5 USPQ2d at 1598 (Fed. Cir. 1988). In re Deuel, 51 F.3d 1552, 1556, 34 USPQ2d 1210, 1214 (Fed. Cir. 1995).

Combinations of known elements are patentable. Even if the Examiner had cited references containing all the elements of the claims, that would not preclude patentability. A new combination of elements can be patented "whether it be composed of elements all new,

partly new or all old." Rosmount, Inc. v. Beckman Instruments, Inc., 727 F.2d 1540, 1546, 221 USPQ 1, 7 (CAFC 1984). In fact:

> Most patentable inventions combine old elements. **The fact that a patent combines teachings from prior art references is irrelevant to the legal determination of obviousness under § 103** and the factual inquiries set forth in Graham .... "The critical inquiry is whether 'there is something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination.' " Fromson v. Advance Offset Plate, Inc ., 755 F.2d 1549, 1556 [225 USPQ 26, 31] (Fed. Cir. 1985) (citation omitted) (emphasis in original) .... Intra Corporation v. Hamar Laser, 662 F. Supp. 1420, 1440-1441, 4 USPQ2d 1337, 1352, 1353 (E.D. Mich. 1987), citations omitted, emphasis added; aff'd, 862 F.2d 320 (CAFC 1988)(unpublished).

***Prima facie* obviousness requires a specific motivation to combine references.** "To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)." MPEP 2142.

No specific motivation to make the claimed combination has been provided. Case law requires that the Examiner provide a specific motivation in the art for combining known elements in order to establish obviousness of the combination.

> "[C]ase law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. ... Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight. ... [Evidence of a suggestion, teaching, or motivation to combine] must be clear and particular. ... Broad conclusory statements regarding the teaching of multiple references, standing alone, are

> not 'evidence.' ... [A] reference-by-reference, limitation-by-limitation analysis fails to demonstrate how the [cited] references teach or suggest their combination ... to yield the claimed invention," and a conclusion of obviousness based on such an analysis "as a matter of law, cannot stand." In re Dembiczak, 175 F.3d 994, 999, 1000, 50 USPQ2d 1614, 1617, 1618 (Fed. Cir. 1999).

No clear, particular suggestion or motivation in the prior art to make the specific combination of a stent, a polymer-therapeutic substance coating on the stent and a PTFE tape wrapped on the outside of the stent as recited in the pending claims has been provided. In the absence of a specific suggestion in the prior art, a rejection identifying individual elements of the claimed combinations is based merely on hindsight in light of Applicant's disclosure. *Prima facie* obviousness has not been established under such conditions, and a rejection based on such an unmotivated combination of references will not stand as a matter of law.

Myers, et al. merely discloses a tubular intraluminal graft comprising a tubular, diametrically adjustable stent having an exterior surface, a luminal surface and a wall having a multiplicity of openings through the wall, and a tubular covering of porous expanded PTFE film affixed to the stent. There is absolutely no mention of incorporating a therapeutic substance (i.e., a drug) into the intraluminal graft.

Choi, et al. on the other hand, discloses generally a polymer formulation in which a "beneficial agent" is incorporated. The polymers exhibit a controlled degree of the erosion in an aqueous environment and thus can be used for making devices and coatings for releasing a beneficial agent as the polymers erode. However, Choi, et al. offer no suggestion that a stent or graft can be coated with the polymers disclosed. Various examples in Choi, et al. are given, none of which include a stent or graft. For example:

> In FIG. 3, a device 10 prepared by using a polymer of the invention, is used for administering a systemically active drug and has an exemplary square shape with dimensions of 3" x 3" x 10 mil.
>
> In FIG. 4, a device 10 is seen for administering an agent 13 at variable rates over a period of time. Device 10 is a multilayered structure comprised of two outer layers 14 and 16, distant from each other with a layer 15 positioned between layers 14 and 16. An agent 13 is dispersed in each layer and it can be the same or different in the layers.

FIG. 5 illustrates another device 10 used as a means for delivering an agent 13 including a drug. Device 10 consists of two layers 14 and 15, each formed of a different polymer having a different bioerosion rate. Layer 14 consists of a polymeric matrix containing a plurality of cells 17 dispersed throughout the matrix. An agent 13 is present in cells 17, which agent is dissolved in a liquid 18 that is a solvent for the agent and a nonsolvent for the polymer. Layer 15 contains particles of a different agent 13 dispersed therein. When device 10 is placed in the environment of use, for example against an animal organ, or in a body cavity, layer 14 gradually bioerodes and releases dissolved agent 13 to the surrounding tissues.

FIG. 6 illustrates a device 10 formed of a bioerodible polymer 12 comprising a multiplicity of microcapsules 19 with each microcapsule having a wall 20 made of an agent release rate controlling material. An agent 13 is housed within microcapsules 19.

In FIG. 7, a device of aid in the healing of injuries is shown comprising a support base layer 21 formed of a breathable impervious material such as cellophane, rubber or polyethylene and the like, with a bioerodible solid polymer 12 containing agent 13, a drug, fixed to base 21. Device 10 is useful for administering drug 13 to the skin, mucosa or an exposed wound.

FIG. 8 depicts a pharmaceutical device particularly adapted for use as a depot implant. Depot implant 10 is manufactured for administering a drug 13 and it is comprised of a pair of layers 14 and 16 having sandwiched therebetween a single layer 15. One advantageous use of the implant is in surgical operations accompanied by severe pain after the operation is completed and the patient regains consciousness. In these cases, when the body is opened for the operation, an implant containing an analgesic can be implanted into the body during the operation to ease pain as it bioerodes and releases the analgesic drug throughout the recovery period.

FIGS. 9 and 10 illustrate devices for delivering drug, which devices have several variables that may be manipulated to control the rate and period of drug release. Referring first to FIG. 9, there is illustrated a device 10 having a cylindrical shape and a passageway 20 extended through the center of device 10 in parallel alignment to the cylindrical axis of device 10. Device 10 is made of a bioerodible polymer 12 for releasing drug within a vagina. Passageway 20 is a means for manipulating the amount of drug released from device 10 by increasing the surface exposed to the fluid of the environment of use thereby influencing the amount of drug released over bioerodible time. FIG. 10 illustrates another means for manipulating the rate and period of drug release from a device 10, and it provides the medical profession with a device for insertion into the natural cavities of the animal body 24, such as the anus 25, where it releases a drug for promoting healing effects.

Referring to FIGS. 11a and 11b, a device 10 is shown for placement in a human eye including an ocular insert 10 consisting of a bioerodible polymer 12 comprising a continuous matrix having particles of drug dispersed therethrough.

In FIG. 12, there is graphically illustrated a device 10 for releasing a drug 13 within a uterus 36 having sides 37 and a fundus uteri 38. Device 10 as shown in cross-section, is a bioerodible intrauterine device having a round tube shaped body made of bioerodible polymer 12 that contains drug 13 for release in uterus 36 concurrently with the bioerosion of polymer 12.

There is no example of a stent or graft in the many embodiments of Choi, et al.

As the cited references do not teach all the elements of the pending claims, and no specific motivation in the prior art to modify and combine the references has been provided, *prima facie* obviousness has not been established. The Examiner is respectfully requested to withdraw this rejection.

2-5) Other Claim Rejections Under 35 U.S.C. § 103

The Examiner rejected various other claims under § 103 by combining Myers and Choi with various other references. As the foregoing shows, the Examiner has not established a *prima facie* case for combining Myers with Choi to render the pending claims obvious. Therefore, the Examiner has not established a *prima facie* case for combing Myers with Choi and then further with a third reference. Furthermore, the claim rejections herein are only of claims dependent on claim 103. Because Applicant has shown above that claim 103 is patentable over Myers in view of Choi, all the claims dependent on claim 103 are also patentable.

viii.

CLAIMS APPENDIX

Claims 103-119 pending at the time of the Final Office Action are attached hereto as an appendix.

ix.

EVIDENCE APPENDIX

None.

x.

RELATED PROCEEDINGS APPENDIX

None.

FEES

The Commissioner is hereby authorized to charge the Appeal fee under 37 C.F.R. §§41.20(b)(2) to Deposit Account No. 50-1225.

If an appropriate payment does not accompany or precede this submission, the Commissioner is hereby authorized to charge any required fees, such as under 37 C.F.R. §§ 1.16 or 1.17, including any petition for extension of time, or to credit any overpayment, to Deposit Account No. 50-1225.

Respectfully submitted,

Date: _____

_____

Guy Cumberbatch, Reg. No. 36,114
Telephone: (773) 818-5603
c/o Rajiv Yadav, Ph.D., Esq.
(949) 250-6801
Registration No. 43,999
Edwards Lifesciences LLC
Law Department
One Edwards Way
Irvine, California 92614
Telephone: (949) 250-6807
Facsimile: (949) 250-6850
Customer No.: 30452

CLAIMS APPENDIX

Claims 1-102 (Canceled)

103. (Previously presented) An implantable drug eluting device that has a compressed undeployed diameter and an expanded deployed diameter, the device comprising:

a radially expandable stent comprising a generally cylindrical wall surface and having a hollow bore extending longitudinally therethrough, wherein the generally cylindrical wall surface comprises a plurality of lateral openings in the wall surface;

a coating comprising a polymer and a therapeutic substance disposed on the wall surface of the stent; and

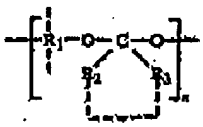
a tubular outer layer comprising expanded, sintered PTFE tape wound about the outer surface of said stent.

104. (Previously presented) The device of claim 103, wherein the polymer is a bioerodible polymer.

105. (Previously presented)The device of claim 104, wherein the bioerodible polymer has an erosion rate of about 2 microns per hour in an aqueous biological environment with a pH between 6-8.

106. (Previously presented)The device of claim 103, wherein the therapeutic substance is paclitaxel or an analog thereof.

107. (Previously presented)The device of claim 103, wherein said polymer comprises a compound having the formula:



wherein R_1 is a member selected from the group of divalent, trivalent and tetravalent radicals consisting of alkylene of 1 to 10 carbons; alkenylene of 2 to 10 carbons; alkyleneoxy of 2 to 6 carbons; cycloalkylene of 3 to 7 carbons; cycloalkylene of 3 to 7 carbons substituted with an alkyl of 1 to 7 carbons, alkoxy of 1 to 7 carbons, an alkylene of 1 to 10 carbons, and an alkenyl of 2 to 7 carbons; cycloalkenylene of 4 to 7 carbons cycloalkenylene of 4 to 7 carbons substituted with an alkyl of 1 to 7 carbons, an alkoxy of 1 to 7 carbons, an alkylene of 1 to 10 carbons, and an alkenyl of 2 to 7 carbons; arylene; and arylene substituted with an alkyl of 1 to 7 carbons, an alkoxy of 1 to 7 carbons, and an alkenyl of 2 to 7 carbons; R_2 and R_3 are selected from the group consisting of alkyl of 1 to 7 carbons; alkenyl of 2 to 7 carbons; alkoxy of 1 to 7 carbons; alkenyloxy of 2 to 7 carbons; alkylene of 2 to 6 carbons; alkenylene of 3 to 6 carbons; alkyleneoxy of 2 to 6 carbons; alkenyleneoxy of 3 to 6 carbons; aryloxy; aralkyleneoxy of 8 to 12 carbons; aralkenyleneoxy of 8 to 12 carbons; oxa; OR_1O with R_1 as defined above; a heterocyclic ring of 5 to 8 carbon and oxygen atoms formed when R_2 and R_3 are taken together; a heterocyclic ring of 5 to 8 carbon and oxygen atoms substituted with an alkyl of 1 to 7 carbons, an alkoxy of 1 to 7 carbons and alkenyl of 2 to 7 carbons formed when R_2 and R_3 are taken together; a fused polycyclic ring of 8 to 12 carbon and oxygen atoms formed when R_2 and R_3 are taken together; a fused polycyclic ring of 8 to 12 carbon and oxygen atoms substituted with an alkyl of 1 to 7 carbons; an alkoxy of 1 to 7 carbons and an alkenyl of 2 to 7 carbons; and wherein at least one of said R_2 and R_3 is a member selected from the group consisting of alkoxy, alkenyloxy and OR_1O; R_2 and R_3 when taken together are a member selected from the group of heterocyclic and fused

polycyclic rings having at least one oxygen atom in the ring; and wherein n is greater than 10.

108. (Previously presented) The device of claim 103, wherein the longitudinal length of said stent remains substantially constant when the stent is expanded from the undeployed diameter to the deployed diameter.

109. (Previously presented) The device of claim 103, wherein the stent comprises a plurality of undulating elements that comprise a spiral.

110. (Previously presented) The device of claim 109, wherein the adjacent turns of the spiral are connected to each other by at least one linear connector.

111. (Previously presented) The device of claim 109, wherein the undulating elements are zigzag elements.

112. (Previously presented) The device of claim 109, wherein the undulating elements are sinusoidal elements.

113. (Previously presented) The device of claim 103, wherein the tape has a thickness of less than about 0.015 inches (0.038 cm).

114. (Previously presented) The device of claim 113, wherein said tape is wound around the stent in 1 to 10 overlapping layers.

115. (Previously presented) The device of claim 103, wherein the stent comprises a self-expanding stent.

116. (Previously presented) The device of claim 115, wherein the self-expanding stent comprises a shape memory alloy.

117. (Previously presented) The device of claim 103 further comprising:

a tubular inner base graft formed of expanded, sintered PTFE, wherein said tubular inner base graft is deployed within the hollow bore of the stent such that the outer surface of the tubular inner base graft is in contact with the inner surface of the stent.

118. (Previously presented) The device of claim 117 further comprising:

PTFE particles deposited between the tubular inner base graft and the tubular outer layer.

119. (Previously presented) The device of claim 118, wherein a bond is formed between the tubular inner base graft and the tubular outer layer by applying heat to an area defined by one of said lateral openings.